SYMPTOM TRIGGERED THERAPY FOR ALCOHOL WITHDRAWAL SYMPTOMS USING REVISED CLINICAL INSTITUTE WITHDRAWAL ASSESSMENT OF ALCOHOL SCALE (CIWA-AR) – A RANDOMIZED CONTROL STUDY

Submitted

BY

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Dissertation submitted to

THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY, CHENNAI,

In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE IN PSYCHIARY

Under the guidance of

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"Symptom triggered therapy for alcohol withdrawal symptoms using revised clinical institute withdrawal assessment of alcohol scale (CIWA-Ar) – a randomized control study"** is a bonafide and genuine research work carried by me under the guidance of Dr. G. Raghuthaman, Prof and Head, Department of Psychiatry, PSGIMS & R, Coimbatore.

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CERTIFICATE BY THE GUIDE

This is to certify that this dissertation entitled **"Symptom triggered therapy for alcohol withdrawal symptoms using revised clinical institute withdrawal assessment of alcohol scale (CIWA-Ar) – a randomized control study"** is a bonafide work done by **Dr. Sushith Sugathan Chennatte** in partial fulfillment of the requirement for the degree of M.D (PSYCHIATRY)

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Abstract:

Background:

Alcohol related withdrawal symptoms are common problems encountered in alcohol dependent patients. Withdrawal symptoms exist in a continuum and there is need for timely treatment of these withdrawal symptoms in order to prevent complicated withdrawal states like Delirium tremens and withdrawal seizures. The treatment is by administration of benzodiazepines and the usual practice is to start patients on an empirical dose, “Fixed schedule treatment”. But there is another method called the “Symptom triggered treatment” for administering benzodiazepines which utilizes a rating scale called the Clinical Institute Withdrawal Assessment Scale (CIWA-Ar), which helps in giving medications according to severity of the withdrawal rating.

Aims of the Study:

To compare between the two regimens for alcohol detoxification namely, the "Symptom triggered treatment" and the "Fixed schedule treatment" for outcome variables: Dose of benzodiazepine, duration of treatment and severity of withdrawal.

Methods:

Prospectively we randomized consenting, consecutive patients, admitted with the diagnosis of alcohol dependence syndrome according to DSM-IV criteria into either of the 2 detoxification treatment methods: 1)Fixed schedule treatment or 2)Symptom triggered treatment.

Results:

The “Symptom triggered treatment” group required 93 mg lesser mean benzodiazepine dose than the “Fixed schedule treatment” group. The mean duration of treatment in the “Symptom triggered treatment” was 2.12 days lesser than the “Fixed schedule treatment.” There was a group of patients who did not require any benzodiazepine during detoxification and they were significantly higher in the “Symptom triggered treatment” group (24%) when compared with the “Fixed schedule treatment” group (4%). No incidences of any complicated withdrawal symptoms during course of detoxification in the sample.

Conclusions:

The Symptom triggered treatment using CIWA-Ar scale may be a safe and better treatment option for patients during alcohol detoxification in terms of lower benzodiazepine dose and shorter duration of treatment.

Introduction:

According to the World Health Organization, there are about 2 billion people in this world who are using alcoholic beverages and among them 76.3 million have diagnosable alcohol related disorders who need treatment.

According to the newly compiled Alcohol Atlas of India, there is an alarming increase in alcohol consumption in the country and also the age of starting alcohol consumption is decreasing at an alarming rate[(1)]

Alcohol withdrawal

Many patients on suddenly stopping or decreasing alcohol intake , would experience alcohol related withdrawal symptoms. Alcohol is a CNS depressant, so the withdrawal symptoms related to alcohol would be more of activation type, like coarse tremors of hands, insomnia, anxiety, increased BP, heart rate, body temperature, respiratory rate, nausea, vomiting, headache etc[(2)].

About 95 % or more of the withdrawal symptoms are of the mild to moderate type with above mentioned symptoms. But around 3-5 % of the patients may experience a complicated withdrawal state[3].

Some of the complicated withdrawal conditions related to alcohol include **Delirium Tremens, withdrawal seizures, Alcoholic Hallucinosis**. Delirium and convulsions carry high **morbidity and mortality** [4] [5].

The treatment of these alcohol withdrawal symptoms is called **detoxification.** Benzodiazepines are the treatment of choice for detoxification [6] and meta-analyses have proved that Benzodiazepines have greater efficacy, and good margin of safety [7][8][9]. Benzodiazepines that are commonly used for detoxification are Chlordiazepoxide, Diazepam or Lorazepam.

It has been shown that the Benzodiazepines not only help to improve the symptoms related to alcohol withdrawal, but that if started in timely manner, it is also helpful in reducing the incidence of complicated withdrawal states like Delirium Tremens and withdrawal seizures[7].

Mechanism of action of the Benzodiazepines is similar to the effect of alcohol; these medications also enhance the effect of the neurotransmitter GABA on the brain. Thus the medication can be initiated and slowly tapered and stopped in order to treat the alcohol related withdrawal symptoms.

Administration of Benzodiazepines

Regarding the administration of Benzodiazepines for treatment of alcohol withdrawal symptoms, the general practice is to administer the medications orally and the initial dose is decided empirically and then it is slowly tapered and stopped. The decision on the initial dosage of the benzodiazepine is decided empirically by taking into consideration the amount of alcohol consumption by the patient and the history of withdrawal symptoms and past history of any complicated withdrawal symptoms in which case a higher dose is started **(9)**.

But some studies have shown that this method sometimes results in using large doses of benzodiazepines and whereas some patients also seem to undergo safe and comfortable withdrawal period without any pharmacological intervention also**(10)**.

But in routine practice most patients receive benzodiazepines during their withdrawal phase [10]. It is also been shown that under dosing of the benzodiazepine medications can lead to complicated withdrawal symptoms in the patient like withdrawal seizures and Delirium Tremens[11].

Thus the determination of the dose of benzodiazepine that has to be started for a patient, who comes in alcohol withdrawal phase, is of very high significance. For this there exists certain alcohol related withdrawal symptom assessment scales with which we can systematically and periodically assess the severity of the withdrawal symptoms and which provides guidelines for administration and dosing of the benzodiazepines accordingly[4] [11] [12][13].

One such validated scale is the revised Clinical Institute Withdrawal Assessment for Alcohol (CIWA-Ar)[12] [13].

The CIWA-Ar Rating Scale

The CIWA-Ar rating scale developed by Sullivan et al, is a validated scale that helps to measure the severity of alcohol related withdrawal symptoms[14]. In addition to that it is also useful in monitoring the clinical course of the withdrawal period and also helps to identify patients at risk of developing complicated withdrawal symptoms like delirium tremens and withdrawal seizures[15][16][17].

The scale is clinician administered and has 10 items consisting of withdrawal symptoms like nausea/ vomiting, Tremor, Paroxysmal sweats, anxiety, agitation, tactile, auditory, visual disturbances, headache and Orientation[14].

Each item is scored in graded manner according to increasing severity, from 0-7, except for Orientation which is scored from 0-4. A total rating score of more than 15 is indicative of a higher risk for developing complicated withdrawal (RR- 3.72; 95% confidence interval 2.82 –4.85). The higher the score, the greater is the risk for complicated withdrawal [18][19][20].

Symptom triggered treatment for Alcohol withdrawal

Studies have shown that the protocol for administering benzodiazepines for treatment of alcohol withdrawal can be standardized based on the CIWA-Ar rating score [(21)].

This is done by administering the CIWA-Ar scale every hour for the patient, during which the benzodiazepine is administered whenever the score is greater than or equal to 10. The rating is continued every hour till the score comes below 10 and after which it is continued every 4^{th} hourly[(21)].

Rating is done totally for a period of first 24 hours in this manner and the next day onwards the total dose of benzodiazepine received on the first day is given in divided doses and then tapered by 10mg daily from the third day onwards [(21)].

This method of detoxification is called **symptom triggered treatment**. This is an efficient method for detoxification as it helps in administering the benzodiazepines in an efficient manner according to the severity of symptoms of the individual patients[(22)].

This is more of an individualized approach in treatment of withdrawal symptoms and may be a better method for calculating the accurate dosage of benzodiazepines to administer for these patients than the treatment as usual, in which the dose is empirically decided[23][24].

However there are only two randomized controlled studies till now that have compared between the symptom triggered approach and fixed schedule treatment. Both these studies had reported that the symptom triggered approach was better in terms of duration and dosage of benzodiazepine administration [23] [24].

Review of Literature:

In Switzerland, **Daeppen et al (2002)** [23] did a prospective randomized double blind placebo controlled trial comparing symptom triggered and fixed treatment schedule for managing alcohol withdrawal symptoms.

They recruited **117** alcohol dependent patients diagnosed according to Diagnostic Statistical Manual- IV criteria and who had taken last alcohol drink within 72 hrs prior to time of admission. Oxazepam was used as the detoxifying agent.

In the Fixed Schedule treatment group, on the first day they received Oxazepam 30mg tablets, 6^{th} hourly, and then on the second and third days they received 15mg, 6^{th} hourly. Also half an hour after taking each tablet, CIWA-Ar was administered and if the score was between **8 and 15**, they received 15mg of oxazepam and if score was **above 15** , they received 30mg of **oxazepam**. The CIWA-Ar rating was done every half an hour until the score came below 8.

In the symptom triggered treatment group, the patients received **placebo** in the same manner as oxazepam in the fixed schedule regimen. And also the patients were monitored with CIWA-Ar **every half an hour** and administered oxazepam accordingly as mentioned above until the CIWA-Ar score came below 8. **Nursing staff** in charge of administering the CIWA-Ar scale and oxazepam were blinded to treatment allocation.

The study revealed a significant reduction in the mean oxazepam dose administered in symptom triggered group (37.5mg) compared to the fixed schedule group (231.4mg) with a p value < 0.001 .

In another study, by **Saitz et al** (1994) [24], which was a prospective randomized double blind placebo controlled trial, used C**hlordiazepoxide**, to compare fixed treatment schedule and symptom triggered treatment.

They randomized **101** patients and allocation was done by a pharmacist who was blinded to the study protocol.

In the fixed schedule treatment, on the first day, patients received 50mg of chlordiazepoxide 6th hourly and on the 2nd and 3rd days they received 25 mg 6th hourly. In addition they were also monitored with CIWA-Ar rating **every hour** and they received chlordiazepoxide **25-100mg** depending on the CIWA-Ar score, whenever it went **above 8**.

In the symptom triggered treatment group, patients received placebo 6th hourly for three days. And in addition they were monitored with CIWA-Ar scale every hour until the score came below 8.

Patients were administered chlordiazepoxide doses ranging from 25-100mg depending on the CIWA-ar scores. **Nurses** who were blinded to treatment allocation decided and administered the chlordiazepoxide according to the CIWA-Ar scale.

This study also revealed a significantly lesser amount of chlordiazepoxide needed in the symptom triggered group (100mg) as compared with the fixed schedule (425mg) with p value <0.001.

Rationale for our study:

The above 2 western studies [23][24], while comparing symptom triggered therapy with fixed regime treatment, used CIWA-Ar scale even in fixed regime treatment arm to give extra benzodiazepine. We believe that this would have contaminated the groups.

Hence, we planned to study the two groups but strictly not using CIWA-Ar to assist the benzodiazepine administration in fixed regime treatment. In fixed regime treatment, the dose of benzodiazepine should be empirically decided and fixed at the beginning itself.

In our study we wanted to adopt the method of using CIWA-Ar for determining the benzodiazepine dose in the symptom triggered group alone.

All the published studies using CIWA – Ar were done in the west and on searching the literature, we did not find any published research from India. Drinking practices vary substantially among different countries and this difference should be taken into account and culture specific treatment measure should be developed [25].

Hence, we decided to see whether symptom triggered therapy is feasible in our culture after giving adequate training to residents and nursing staff.

AIMS:

In patients with alcohol dependence syndrome, during the detoxification phase, to assess whether **Symptom triggered treatment (STT)** would differ from **Fixed schedule treatment (FST)** with respect to :

1) Dose of benzodiazepines needed to manage withdrawal symptoms

2) Duration of detoxification and

3) Complications and severity of withdrawal symptoms.

METHODOLOGY:

All the consecutive patients, between the ages of 16 and 65 years, admitted to our psychiatry ward with the diagnosis of alcohol dependence syndrome, were screened for study inclusion.

After explaining the study protocol, we got written informed consent from the patient and the family member who had accompanied the patient. Patients who gave voluntary consent would enter the study and patients who are not having capacity to give consent because of delirium were included only if the family members give valid consent.

Consenting patients were interviewed by the researcher using Structured Clinical Interview for DSM IV (SCID)[26] and only patients fulfilling DSM IV criteria for alcohol dependence syndrome were included.

In patients who had delirium, if the causes for delirium were found to be other than alcohol withdrawal, then they were excluded from the study.

Eligible patients were interviewed to get demographic characteristics, medical co-morbidities, smoking status and use of any other substances or prescribed drugs during the last 30 days.

We used the Severity of Alcohol Dependence Questionnaire (SADQ) to assess the severity of dependency. This is a 20-item, self-rated questionnaire, which has been developed to provide a brief and replicable method of assessing the severity of alcohol dependence syndrome [27].

As SADQ is not validated, we have translated the questions from English to Tamil and back to English and only the questions which retain the original meanings were used in the Tamil version. For other questions, we repeated the whole procedure of translations till valid translated Tamil version was obtained. We used the Tamil version of **SADQ** on all patients enrolled into the study.

CIWA – Ar was administered to all the patients to get the baseline score.

Then by using computer generated randomization technique, we randomized the patients into one of the 2 detoxification regimes: 1) Fixed schedule treatment or 2) Symptom triggered treatment.

1) **Fixed schedule treatment (FST):**

For patients randomized to this group, the admitting psychiatrist decides about the initial dose of benzodiazepine (Chlordiazepoxide or Lorazepam). From day 3, the dose was reduced and in case of Chlordiazepoxide the reduction was by 10mg per day and if it was Lorazepam the reduction was by 1mg per day.

2) **Symptom triggered treatment (STT):**

The treatment team (nurse staff/resident) on the ward administered CIWA-Ar immediately after the patient was recruited into the study. If the score was above 10, the patient was given 20mg of Chlordiazepoxide.

Thereafter, CIWA-Ar was administered every hour till the score reached below 10 and maintained score less than 10 on total of three successive readings. After that CIWA – Ar rating scale was administered once in 4 hours and if any time the score went above 10, the scale administration was rescheduled to once an hour again.

Any time the score went above 10, the patient received 20mg of Chlordiazepoxide orally. The total amount of Chlordiazepoxide that the patient got on Day 1 was given on the second day as divided doses. From day 3, the dose of Chlordiazepoxide was tapered by 10mg every day.

For patients where Chlordiazepoxide was contraindicated for medical reasons like hepatic dysfunction, we used equivalent dose of Lorazepam i.e. 1mg each time the score was 10 or above, and tapered the daily dosing by 1mg daily from the third day onwards.

This method of benzodiazepine administration had been validated earlier [(6)].

From the second day onwards CIWA – Ar was administered for both the groups, every morning between 8 am and 10 am, by an investigator who was blind to the treatment allocation for a period of 7 days.

Training nursing staff and residents:

Before starting this study, we trained the nursing and residents in administering CIWA – Ar scale among patients with varying severity of alcohol withdrawal state. At the end of the training, we found that the single measure intra class correlation co-efficient was 0.898 indicating a high level of agreement for all the items of CIWA – Ar [28].

Sample Size Determination

We sampled 25 patients who were admitted for alcohol dependence syndrome in our psychiatry ward. In this group, the mean dose of chlordiazepoxide administered was 139.6 mg (standard Deviation 70.44) and this was by the fixed schedule method.

We hypothesized that in our prospective study, by following symptom triggered method, if the mean dose of chlordiazepoxide could be reduced by at least 50mg, we would consider that as a clinically significant difference.

By using the above figures and keeping α at 0.05 and power of the study at 90, we estimated the sample size with the formula:

$$\mathbf{2 \times [SD \times (Z\alpha + Z\beta) / Mean\ difference]^2},$$

(SD = 70.444, $Z\alpha = 1.96$, $Z\beta = 0.84$, and Mean difference = 50 mg).

By this calculation, we found that we needed 31 patients in each group.

Outcome measures:

Primary outcomes:

1. Amount of benzodiazepines in both the groups; we would measure the mean dose of benzodiazepines administered.

2. The duration of detoxification period: The mean time duration of benzodiazepine administration.

3. CIWA – Ar ratings in both the treatment groups.

Secondary outcomes:

1. Withdrawal complications like, delirium tremens and rum fits.

Statistical Analysis

We performed statistical analysis with PASW (SPSS) version 18.0 for Windows.

We compared the Fixed schedule treatment group and the symptom triggered group in the following variables: Age, Marital status, socio economic status, SCID criteria, SADQ scores, smoking status, co morbid medical illness, CIWA-Ar scores, Benzodiazepine doses, duration of detoxification phase and complicated withdrawal.

We used descriptive statistics to get the mean and standard deviation of continuous variables. Student t test was used to compare continuous variables like age, socioeconomic status, SADQ total scores, CIWA-Ar baseline scores, total equivalent benzodiazepine doses and number of detoxification days.

We used chi-square test to compare dichotomous variables like marital status, smoking status, other substance use status, co morbid medical illness status, SCID criteria, dichotomized CIWA-Ar score with cut off as10, complicated withdrawal, and patients who needed no benzodiazepine.

We used Mann Whitney test (non Parametric test) to compare variables like daily mean benzodiazepine doses and daily CIWA-Ar scores between the Fixed schedule treatment group and the Symptom triggered group. We used Mann Whitney test also to compare total benzodiazepine equivalent dose between the delirium and non delirium groups.

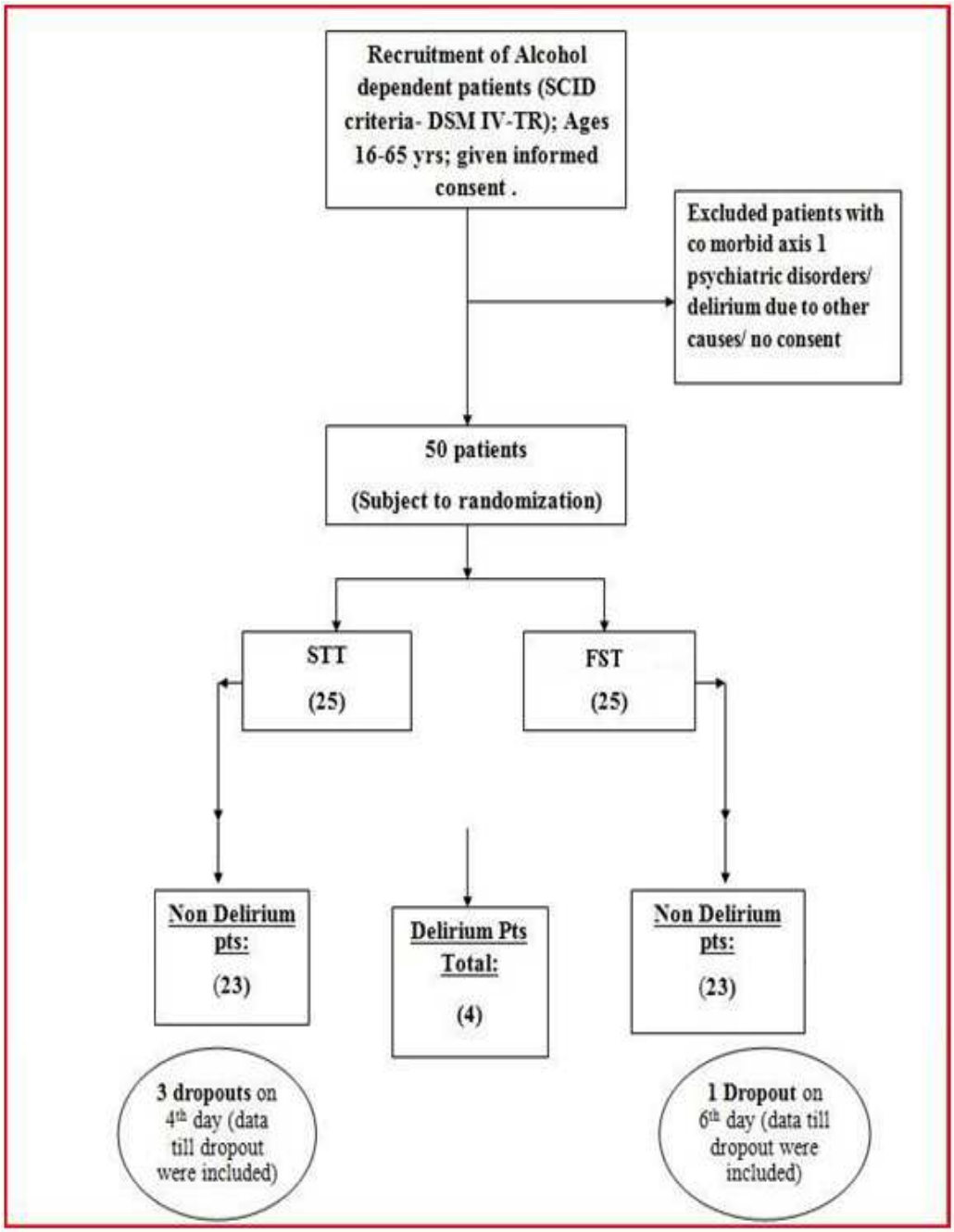
Results:

A total of 50 patients who fulfilled the inclusion criteria were randomly assigned to either the "Fixed schedule treatment" **(FST)** or the "Symptom triggered treatment" **(STT)** groups. Thus there were 25 patients in each of these groups.

Dropouts:

There were a total of 4 dropouts in the study. One dropout was from the "Fixed schedule treatment" group who dropped out on the 6^{th} day and remaining three dropouts were from the "symptom triggered treatment" group, who dropped out on the 4^{th} day. The reasons for dropout for all these patients were discharge from hospital before completing detoxification. Their data till their drop were used for analysis. **(Fig 1)**

Fig 1:Flow chart for study recruitment and characteristics of study groups



Socio demographic details:

All the patients were of male gender and the mean age of the patients in the whole sample was 38.3 yrs (SD- 9.2). There was no statistically significant difference between the mean ages in the Fixed schedule treatment group (37.8) and the Symptom triggered group (38.9). (**Table 1**)

Table 1 :Age characteristics in the sample; (STT- symptom triggered treatment)

Group	**No. of Pts**	**Mean Age**	**Std. Deviation**
FST	25	37.80	9.721
STT	25	38.92	8.976
Total	50	38.36	9.277

Regarding marital status, there were 20 (80%) patients in the Fixed schedule treatment group and 18 (72%) patients in the symptom triggered group who were married and the rest were either single, separated or divorced.**(Table 2).** There was no statistically significant difference between the two groups regarding marital status.

Table 2 : Marital Status in the sample

Group	Marital Status			
	Married No. (%)	**Single No. (%)**	**Separated No. (%)**	**Divorced No. (%)**
FST	20 (80)	3 (12)	2 (8)	0 (0)
STT	18 (72)	3 (12)	3 (12)	1 (4)
Total	38 (76)	6 (12)	5 (10)	1 (2)

Out of the total sample, 3 patients were unemployed and for the rest of the 47 patients, the mean monthly salary was Rs. 13,019 (SD- 9337.8). There was no statistically significant difference regarding the socio-economic status between both the groups.

Relevant clinical variables of the study population:

The no. of smokers were higher (80%) in the Fixed schedule treatment group and this was statistically significant (**p value = 0.03**) **(Table 3)**.

Whereas the rate of "other substance use" (like chewing betel nut, tobacco etc.) was higher in the Symptom triggered treatment group (40%) than in the treatment as usual group(24%), but this difference was not statistically significant**(Table 4)**.

There was no statistical significance regarding the presence of medical illness between the Fixed schedule treatment and the symptom triggered treatment groups **(Table 5)**.

Table 3: No. of smokers in each group

Group *	Smoking No. of Pts (%)	
	yes	no
FST (25)	20 80.0%	5 20.0%
STT (25)	13 52.0%	12 48.0%
Total (50)	33 66.0%	17 34.0%

*Chi-Square = 4.367, df =1, p=0.037

Table 4: No. of other substance users in both the groups

Group	Other subs use No. of Pts (%)	
	yes	no
FST (25)	6 24.0%	19 76.0%
STT (25)	10 40.0%	15 60.0%
Total (50)	16 32.0%	34 68.0%

Table 5: Co morbid Medical illness in both the groups

Group	Medical Illness No. of Pts (%)	
	yes	No
FST (25)	9 36.0%	16 64.0%
STT (25)	8 32.0%	17 68.0%
Total (50)	17 34.0%	33 66.0%

Profile of Alcohol dependence in the sample:

All the patients fulfilled at least 5 out of the 7 items in the DSM IV-TR criteria for alcohol dependence syndrome. Majority of the patients fulfilled 6 or 7 of the DSM IV-TR criteria **(Table 6).** There was no statistically significant difference between the fulfillment of SCID criteria between the "treatment as usual" and "symptom triggered groups".

Table 6: SCID Criteria in both the groups

Group	No. of Criteria fulfilled in SCID No. of pts (%)		
	5	6	7
FST (25)	0 (0)	12 (48)	13 (52)
STT (25)	1 (4)	13 (52)	11 (44)
Total (50)	1 (2)	25 (50)	24 (48)

The severity of alcohol dependence measured by the SADQ scale was analyzed for both the groups **(Table 7)**.

The mean SADQ score for the sample as a whole was 31.1(SD- 9.5), which classifies for severe alcohol dependence (the cut off being 31 and higher on SADQ score).

When comparing the mean SADQ scores between the “Fixed schedule treatment” and “symptom triggered treatment”, they were equal in severity in both the groups and there was no statistically significant difference between the two groups (p value = 0.7).

Table 7: Mean SADQ (total) scores in each group

Group	Mean SADQ Total	Std. Deviation
FST (25)	31.52	9.980
STT (25)	30.76	9.329
Total (50)	31.14	9.568

The mean baseline CIWA-Ar score in the sample as a whole was 9.2 (SD- 7) **(Table 8).** There was no statistically significant difference between the mean baseline CIWA-Ar scores in both the groups (p value = 0.6).

The number of patients who had baseline CIWA-Ar score of above 10 in the Fixed schedule treatment group were 9 (36%), and those in the symptom triggered treatment group were 13(52%) . But this difference was not statistically significant**(Table 9)**.

Table 8: Mean baseline CIWA-Ar scores in both the groups

Group	Mean CIWA-Ar Baseline	Std. Deviation
FST (25)	8.72	7.738
STT (25)	9.72	6.426
Total (50)	9.22	7.057

Table 9 : No. of patients according to baseline CIWA-ar scores with cut off as 10 in both the groups.

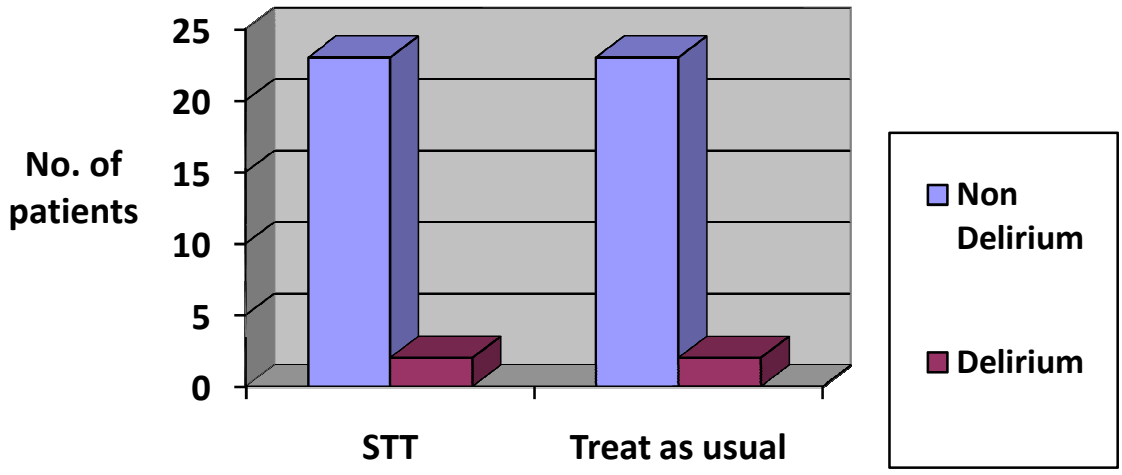
Group	Ciwa-Ar baseline	
	<10 No. of Pts (%)	>10 No. of Pts (%)
FST (25)	16 (64.0%)	9 (36.0%)
STT (25)	12 (48.0%)	13 (52.0%)
Total (50)	28 (56.0%)	22 (44.0%)

Hence, at baseline, the severities of alcohol dependence syndrome and withdrawal symptoms are equal in both the “Fixed schedule treatment” group and “Symptom triggered treatment”

Delirium tremens:

Four patients had delirium tremens; 2 in “Fixed schedule treatment” and 2 in “Symptom triggered treatment”.(**Fig 2**)

Fig 2: No. of Delirium and non delirium patients in the treatment groups



Benzodiazepene dosage:

Only 2 patients in our study sample received lorazepam (1in each of the treatment groups); hence we converted the dose of lorazepam into chlordiazepoxide equivalents. (1mg of lorazepam= 20mg of chlordiazepoxide)

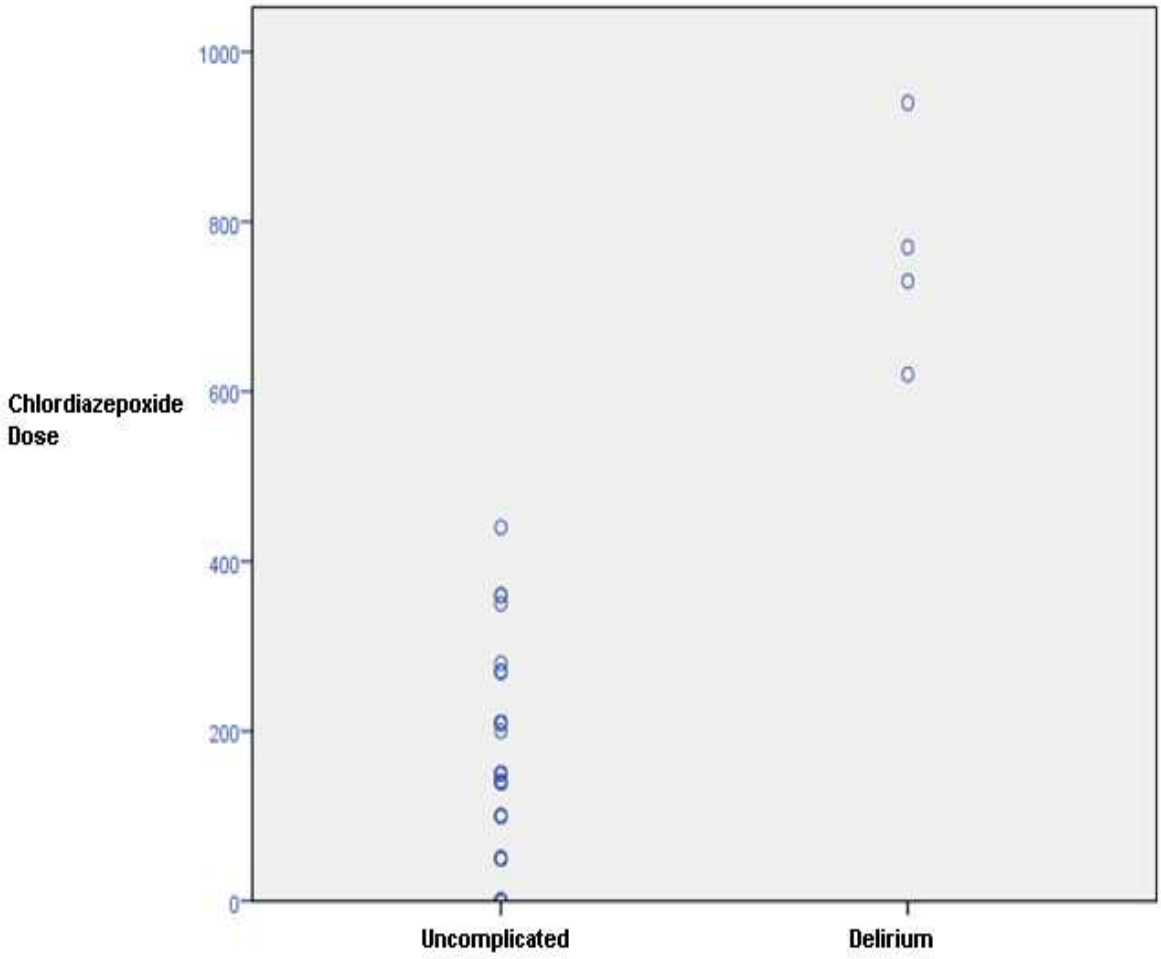
In the whole sample, the **mean total benzodiazepine dosage** was significantly higher among the delirium tremens patients as compared to that in the non delirium (uncomplicated withdrawal) patients **(Table 10)**, which resulted in skewing of the data distribution **(Fig 3)**. Therefore they were analyzed separately.

Table 10: Comparison of mean total BZD equivalent dose in delirium and non delirium patients.

Group *	No. of Patients	Mean Total BZD Eq. Dose	Std. Deviation
Non Delirium	46	147.39	106.592
Delirium	4	765.00	132.791

*Chi-Square= 3.323, df=1, p ***value = 0.001.***

Fig 3 : Total Benzodiazepine equivalent doses in the delirium and non-delirium group of patients.



In the non- delirium patients, the mean total benzodiazepine equivalent dose was significantly lower in the symptom triggered group (100.8mg of chlordiazepoxide), with p value of **0.002**. **(Table 11).**

Table 11: Mean total Benzodiazepine dose in both the groups among non delirium patients.

Group	No. of non delirium patients	Mean Total Benzodiazepine dose (mg)	Std. Deviation
FST	23	193.91	90.541
STT	23	100.87	102.554
Total	46	147.39	106.59

*t(44)=3.261, p=0.002

There were 4 patients with delirium tremens, but there was no statistically significant difference in the mean total benzodiazepine doses between the "Fixed schedule treatment" and "symptom triggered treatment " **(Table 12)**.

Table 12: Mean total BZD Equivalent dose in both the groups among the delirium patients.

Group	No. of delirium pts	Mean Total Benzodiazepine dose (mg)	Std. Deviation
FST	2	675.00	77.782
STT	2	855.00	120.208

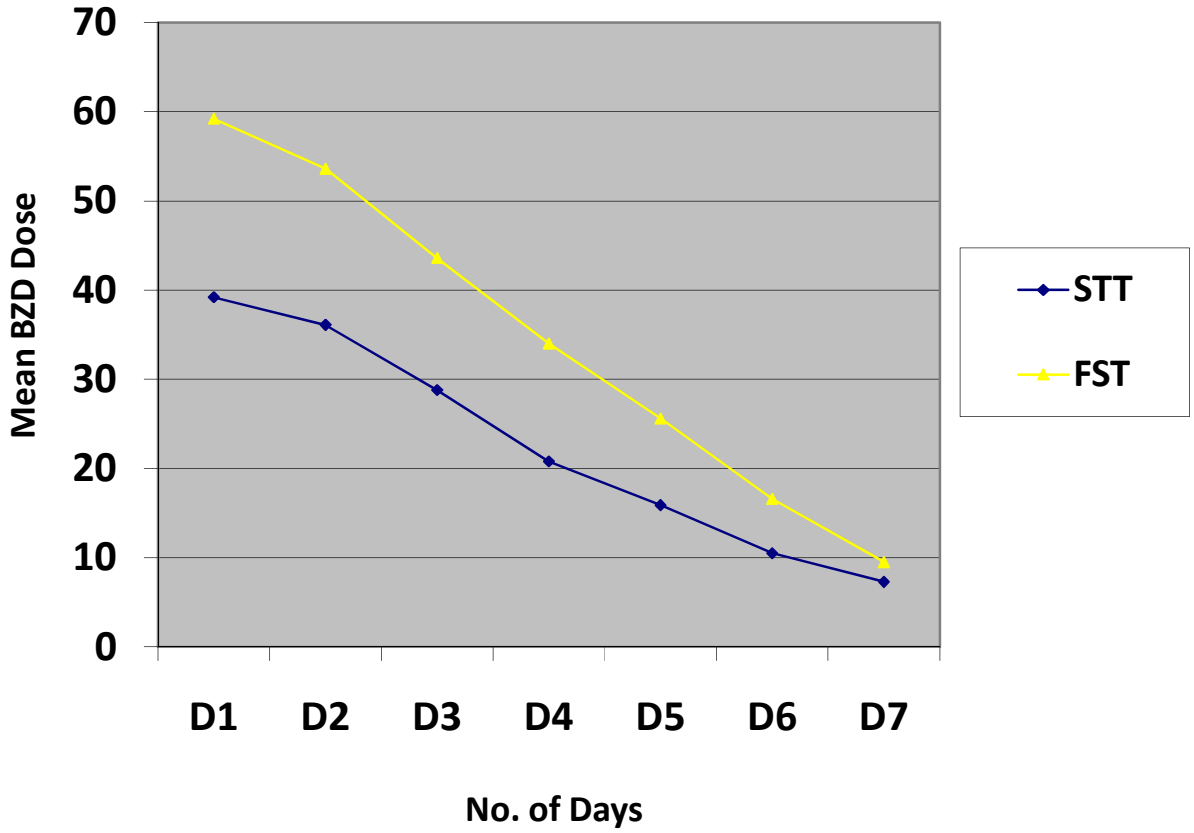
When comparing **daily mean benzodiazepine dosages** between the two groups, from day 1 to day 7, the symptom triggered treatment group had consistently lower mean doses in all the days. The difference was also statistically significant in all the days except in day 7 **(Table 13, Fig 4)**.

Table 13: Comparison of Total mean daily BZD doses in both the groups.

Day	**Total Mean Dose (mg)**	**Mean Total Dose in FST (mg)**	**Mean Total Dose in STT (mg)**	**Chi square value** (df =1)	**p value**
1	49.2	59.2	39.2	3.890	0.000 *
2	44.8	53.6	36.1	3.245	0.001 *
3	36.2	43.6	28.8	3.216	0.001 *
4	27.5	34	20.8	3.118	0.002 *
5	20.8	25.6	15.9	2.951	0.003 *
6	13.7	16.6	10.5	2.171	0.03 *
7	8.5	9.5	7.3	1.190	0.23

* ***p value significant*** *(< 0.05)*

Fig 4: *Daily mean total BZD doses in each of the treatment groups(symptom triggered treatment and Fixed schedule treatment)*



“Zero” benzodiazepines:

There were totally 7 patients who did not receive benzodiazepine at all in the sample. The number of patients who did not require benzodiazepines was significantly higher in the “symptom triggered treatment” group than in the “Fixed schedule treatment” group **(P value = 0.049) (Table 14)**.

Table 14: Comparison of patients who didn’t receive benzodiazepines

Group	No. of Pts (%)	
	No Benzodiazepine administered	Benzodiazepine administered
FST (25)	1 (4.0%)	24 (96.0%)
STT (25)	6 (24.0%)	19 (76.0%)
Total (50)	7 (14.0%)	43 (86.0%)

CIWA-Ar daily scores :

There was no statistically significant difference in the daily progression of the withdrawal symptom severity when comparing the daily CIWA-Ar scores between the Fixed schedule treatment and the symptom triggered groups.**(Table 15)**

Table 15: Comparison of daily CIWA-Ar scores between the treatment as usual and symptom triggered groups.

		CIWA-Ar Scores						
Group		**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
FST	**N**	25	25	25	25	24	23	23
	Mean	8.72	7.20	3.80	2.32	1.38	1.52	1.65
	(SD)	(7.738)	(7.588)	(6.671)	(3.805)	(2.300)	(2.333)	(2.979)
STT	**N**	25	25	25	25	22	22	22
	Mean	9.72	4.24	3.16	3.20	1.95	1.77	1.45
	(SD)	(6.426)	(3.992)	(4.365)	(4.282)	(3.885)	(3.054)	(2.521)
Total	**N**	50	50	50	50	46	45	45
	Mean	9.22	5.72	3.48	2.76	1.65	1.64	1.56
	(SD)	(7.057)	(6.184)	(5.589)	(4.033)	(3.136)	(2.681)	(2.735)

***No statistically significant difference in the scores.**

Duration of Detoxification:

When comparing the number of days of detoxification between the Fixed schedule treatment group and the Symptom triggered treatment group, the mean number of days for detoxification was significantly lower in the symptom triggered treatment group **(p value = 0.005)**. **(Table 16).**

Table 16: Comparison of the mean no. of Detoxification days between the treatment as usual and symptom triggered groups.

Group *	Mean Detoxification Days	Median	Std. Deviation
FST	6.12	6	1.740
STT	4.00	5	3.122
Total	5.06	5	2.721

*t(48)=2.965, p=0.005

Discussion:

This prospective randomized controlled study proved our hypotheses that, **Symptom triggered treatment** using CIWA-Ar scale for alcohol withdrawal would reduce the dose of benzodiazepine needed and also shorten the detoxification duration.

We had recruited a homogenous patient population who qualified for Alcohol dependence syndrome according to SCID and who had severe dependency as rated by SADQ.

As in the routine clinical practice, all the patients were male with mean age of 38 years. Both the ‘Fixed Schedule Treatment’ group and ‘Symptom triggered treatment’ group were comparable with respect to sociodemograhic factors and more importantly in the severity of dependency.

The mean SADQ score was 31.1 (SD- 9.5), which indicates that the addiction to alcohol was at a severe level [27]. There was no difference in the severity of addiction as measured by SADQ and the severity of withdrawal symptoms as measured by CIWA-Ar scale at baseline between the "Fixed schedule treatment" and "Symptom triggered treatment" groups. Randomization would have minimized other confounding variables.

The Symptom triggered treatment group required 93mg (mean) lesser chlordiazepoxide dose than the Fixed schedule treatment group. This difference in the requirement of benzodiazepine dose was clinically and statistically significant from the day1 and it persisted till the end of the study.

Another interesting finding, which is also statistically significant, is that **24% of patients in 'Symptom triggered treatment' group and 4% in 'Fixed schedule treatment' group didn't require any benzodiazepine.** Also, **the symptom triggered treatment group took 2.12 days (mean) lesser to complete the detoxification process.**

CIWA –Ar ratings was done every day morning by an independent assessor who was not part of the investigative team. The mean score of CIWA-Ar for both groups was similar on all days, which informs that the effectiveness of controlling the withdrawal symptoms was equal in both the treatment arms.

The 4 patients who had delirium tremens had delirium from the beginning of their recruitment and none of the patients developed any complicated withdrawal symptoms (delirium tremens, seizures, hallucinations) during the study period. All the 4 patients recovered from delirium tremens at the end of the study.

Sixty six (66%) of the study population were smokers and this was more represented in the in the fixed schedule treatment group (80%) than in the symptom triggered treatment group (52%), but this might not have affect our main results as we are looking only for alcohol related withdrawal symptoms.

Our results are comparable with the western studies which also showed that the symptom triggered treatment required less doses of benzodiazepine. In a randomized double blind controlled study, the symptom-triggered group received 100 mg of chlordiazepoxide, and the fixed dose schedule group received 425 mg [24]. Surprisingly, as the western study, our symptom triggered treatment group also got almost the same mean chlordiazepoxide dose: 100.87mg.

However, the mean dose in our fixed dose schedule group was 193.91mg, which was much smaller. This difference could be due to differences in the method of administration of fixed dose regimen; in the earlier study, they have a fixed starting of chlordiazepoxide as 200mg and in addition subjects received extra chlordiazepoxide whenever the CIWA-Ar score went above 8 [24].

In our study, the mean duration of detoxification was significantly lower in the symptom triggered treatment group (4 days) when compared with fixed schedule treatment group (6.12 days). Similar significant difference was seen in earlier studies also. Both Daeppen et al (2002) and Saitz et al (1994) adopted a rapid detoxification procedure; benzodiazepines were tapered and stopped within 3 days. Still they showed that symptom triggered treatment took lesser hours than fixed schedule treatment to complete the detoxification [23][24].

In a larger RCT placebo controlled study done in Switzerland, authors found that a total of 61% of patients in symptom triggered group did not require benzodiazepine at all [23].

Another research done on 203 problem drinkers admitted to a general hospital found that 46% did not experience any significant withdrawal symptoms that require any form of pharmacological interventions [29]. In our study a total of 28% did not require benzodiazepine to manage their withdrawal symptoms (24% in the symptom triggered group and 4% in the fixed schedule treatment group).

This estimate is lower than the earlier studies and this could be because our patient group had qualified for alcohol dependence with higher severity of addiction needing admission in a Psychiatric setting. However, our study also has confirmed the earlier conclusions that a group of patients do not require benzodiazepine during the withdrawal phase.

Fixed predetermined dose of benzodiazepine regimes may subject many patients to unnecessary medication, overdoses and excessive sedation. This also may prolong the detoxification phase, hospitalization period and increase the cost. Literature on alcohol research argues for non pharmacologic interventions in acute withdrawal [10][11].

CIWA-Ar scale in routine practice:

CIWA-Ar is simple to learn and administer and we have successfully trained nursing staff and residents in using this[28].

Despite of research support, even in the west, symptom-triggered regimens are not used widely; fixed-schedule chlordiazepoxide constituted the most commonly prescribed medication regimen for the treatment of alcohol withdrawal [24].

Most of trials with CIWA-Ar were done in detoxification settings; however we could find 2 studies done in general hospital settings which also proved that CIWA-Ar protocol helped in safe and effective detoxification [30][31]. A Physician could advice nurses to assess patients using CIWA-Ar at regular intervals on the first day of hospital admission. This can be done on patients whom the physician suspect having alcohol problems and likely to develop withdrawal symptoms.

Limitations:

1. As our study is not a double blind study there is a possibility of investigator bias. By carefully adhering to the study protocol, we tried to overcome this bias. In the ‘fixed schedule treatment’ group, the doses of benzodiazepines were decided by the primary treating psychiatrists who were not part of the investigative team and they were unaware of our hypotheses. In ‘Symptom triggered treatment” group, the dose of benzodiazepine was decided by the structured administration of CIWA –Ar scale. To further reduce the bias, the daily morning rating of CIWA –Ar was done by an independent assessor, who was unaware of the treatment allocation.

2. Complicated withdrawal symptoms like delirium tremens, withdrawal seizures and alcoholic hallucinosis were poorly represented in our sample. However no complicated withdrawal symptoms occurred after recruitment suggests that symptom triggered treatment effectively prevented them.

3. The study setting happened in psychiatry ward where we have psychiatry residents and nursing staff with psychiatry skills. Hence, we are not sure whether same outcome could be expected in other medical settings.

4. We were not able to achieve the target sample size of 62 patients owing to time constraints. But with the current sample size itself we were able to obtain statistical and clinical significance in the outcome variables between the two treatment regimens.

CONCLUSION

As per our results we are able to see that there was a significant decrease in the dosage of benzodiazepines that was required for detoxification when using the symptom triggered method as against the fixed schedule treatment. Thus symptom triggered approach would be helpful in preventing excess of sedation that occurs in some patients when the benzodiazepine dose is more than what is actually needed.

Also our results show that there were a group of patients who did not require any benzodiazepine in the symptom triggered regimen, who would have been otherwise started on benzodiazepines if they were on fixed regimen treatment.

There was also no significant difference in the withdrawal severity in all the days throughout the detoxification period between both the treatment groups. And there were no incidents of any complicated withdrawal symptoms during the course of detoxification, indicating that symptom triggered regimen can be considered as a safe alternative for detoxification.

Our results also shows a significant shorter duration of detoxification period itself in the patients on symptom triggered regimen compared to fixed schedule treatment group. This could mean shorter duration of hospital stay and cutting costs for the patient and probably better patient satisfaction. At the background of a difficult withdrawal phase, the patients could perceive the care to be more satisfying, if they are monitored regularly with CIWA-Ar as in the symptom triggered treatment.

Symptom triggered treatment seems to be a favorable, safe and effective method of detoxification for alcohol related withdrawal symptoms in patients admitted in an In-patient hospital set up with nursing staff or residents who are trained in using the CIWA-Ar to administer the benzodiazepines.

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Appendix 1:

SCID-I Version 2.0 (DSM-IV) Alcohol Use Disorder (FEB 1996 FINAL) E. 1
(REVISED AUGUST 1998)

E. SUBSTANCE USE DISORDERS

SCREEN Q#1 E1a

ALCOHOL USE DISORDERS (LIFETIME)

YES ☐ NO ☐

IF SCREENING QUESTION #1 ANSWERED "NO" CHECK HERE ☐ AND SKIP TO *NON-ALCOHOL SUBSTANCE USE DISORDERS, *E.10

IF NO: GO TO NON-ALCOHOL USE DISORDERS *E.10

IF SCREENER NOT USED OR IF QUESTION #1 IS ANSWERED "YES", CONTINUE:

What are your drinking habits like? (how much do you drink?) (has there ever been a time in your life when you had five or more drinks on one occasion?)

When in your life were you drinking the most? (How long did that period last?)

RECORD DATE OF HEAVIEST USE AND DESCRIBE PATTERN: E1b E1c

_____

_____

During that time. . .

how often were you drinking?

what were you drinking? How much?

During that time. . .

did your drinking cause problems for you?

did anyone object to your drinking?

IF ALCOHOL DEPENDENCE SEEMS LIKELY, CHECK HERE ☐ AND SKIP TO * ALCOHOL DEPENDENCE, *E. 4.

IF ANY INCIDENTS OF EXCESSIVE DRINKING OR ANY EVIDENCE OF ALCOHOL-RELATED PROBLEMS, CONTINUE WITH *ALCOHOL ABUSE, * ON NEXT PAGE.

IF NEVER HAD ANY INCIDENTS OF EXCESSIVE DRINKING AND THERE IS NO EVIDENCE OF ANY ALCOHOL-RELATED PROBLEMS, SKIP TO *NON-ALCOHOL SUBSTANCE USE DISORDERS, * E. 10.

?=inadequate information 1=absent or false 2=subthreshold 3=threshold or true

ALCOHOL DEPENDENCE	ALCOHOL DEPENDENCE CRITERIA					
I'd now like to ask you some more questions about your drinking habits.	A maladaptive pattern of alcohol use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following occurring at any time in the same twelve month period: NOTE: CRITERIA FOR ALCOHOL DEPENDENCE ARE NOT IN DSM-IV ORDER					
Have you often found that when you started drinking you ended up drinking much more than you were planning to? IF NO: What about drinking for a much longer period of time than you were planning to?	(3) alcohol is often taken in larger amounts OR over a longer period than was intended	?	1	2	3	E7
Have you tried to cut down or stop drinking alcohol? IF YES: Did you ever actually stop drinking altogether? (How many times did you try to cut down or stop altogether?) IF NO: Did you want to stop or cut down? (Is this something you kept worrying about?)	(4) there is a persistent desire OR unsuccessful efforts to cut down or control substance use	?	1	2	3	E8
Have you spent a lot of time drinking, being high, or hung over?	(5) a great deal of time is spent in activities necessary to obtain alcohol, use, or recover from its effects	?	1	2	3	E9

?=inadequate information 1=absent or false 2=subthreshold 3=threshold or true

IF NOT ALREADY KNOWN: Has your drinking ever caused any psychological problems like making you depressed or anxious, making it difficult to sleep, or causing "blackouts?" IF NOT ALREADY KNOWN: Has your drinking ever caused significant physical problems or made a physical problem worse? IF YES TO EITHER OF ABOVE: Did you keep on drinking anyway?	(7) alcohol use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol (e.g., continued drinking despite recognition that an ulcer was made worse by alcohol consumption)	?	1	2	3	E11
Have you found that you needed to drink a lot more in order to get the feeling you wanted than you did when you first started drinking? IF YES: How much more? IF NO: What about finding that when you drank the same amount, it had much less effect than before?	(1) tolerance, as defined by either of the following: (a) a need for markedly increased amounts of alcohol to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of alcohol	?	1	2	3	E12
Have you ever had any withdrawal symptoms when you cut down or stopped drinking like . . . . . . sweating or racing heart? . . . hand shakes? . . . trouble sleeping? . . . feeling nauseated or vomiting? . . . feeling agitated? . . . or feeling anxious? (How about having a seizure or seeing, feeling, or hearing things that weren't really there?)	(2) withdrawal, as manifested by either (a) or (b): (a) at least TWO of the following: • autonomic hyperactivity (e.g., sweating or pulse rate greater than 100) • increase hand tremor • insomnia • nausea or vomiting? • psychomotor agitation • anxiety • grand mal seizures • transient visual, tactile, or auditory hallucinations or illusions	?	1	2	3	E13
IF NO: Have you ever started the day with a drink, or did you often drink or take some other drug or medication to keep yourself from getting the shakes or becoming sick?	(b) alcohol (or substance from the sedative/hypnotic/anxiolytic class) taken to relieve or avoid withdrawal symptoms					E14

?=inadequate information 1=absent or false 2=subthreshold 3=threshold or true

IF UNKNOWN: When did (SXS CODED "3" ABOVE) occur? (Did they all happen around the same time?)

AT LEAST THREE DEPENDENCE ITEMS CODED "3" AND ITEMS OCCURRED WITHIN THE SAME TWELVE MONTH PERIOD

1 3 E15

IF ALCOHOL ABUSE QUESTIONS (PAGES E.1-E.3) HAVE NOT YET BEEN ASKED, GO TO PAGE E.1. AND CHECK FOR ABUSE.

IF ABUSE QUESTIONS HAVE BEEN ASKED AND ABUSE IS PRESENT, CODE "3" OTHERWISE, IF QUESTIONS HAVE BEEN ASKED AND ABUSE IS NOT PRESENT, GO TO *NON-ALCOHOL USE DISORDERS, *E. 10.

ALCOHOL DEPENDENCE GO TO *CHRONOLOGY E. 7

1 3 E16

GO TO *NON-ALCOHOL USE DISORDER, *E. 10

ALCOHOL ABUSE

ALCOHOL ABUSE CHRONOLOGY

How old were you when you first had (ABUSE SXS CODED "3"?)

Age at onset of Alcohol Abuse (CODE 99 IF UNKNOWN) -- -- E17

Criteria for Alcohol Abuse met at any time in the past month

? 1 3

IF UCLEAR: During the past month, have you had anything at all to drink?

IF YES: Tell me more about it. (Has your drinking caused you any problems?)

PAST ABUSE CURRENT ABUSE E18

GO TO *NON-ALCOHOL USE DISORDER, * E. 10

?=inadequate information 1=absent or false 2=subthreshold 3=threshold or true

CHRONOLOGY FOR DEPENDENCE

How old were you when you first had (LIST OF ALCOHOL DEPENDENCE OR ABUSE SXS CODED "3")?	Age at onset of Alcohol Dependence or Abuse (CODE 99 IF UNKNOWN)		—	—	E19
IF UNCLEAR: During the past month, have you had anything at all to drink? IF YES: Tell me more about it. (Has your drinking caused you any problems?)	Full criteria for Alcohol Dependence met at any time in past month (or never had a month without symptoms of Dependence or Abuse since onset of Dependence)	?	1	3	E20

CURRENT DEPENDENCE

GO TO †REMISSION SPECIFIERS* E. 8

Indicate if: E21

1. With Physiological Dependence (current evidence of tolerance or withdrawal)

2. Without Physiological Dependence (no current evidence of tolerance or withdrawal)

NOTE SEVERITY OF DEPENDENCE FOR WORST WEEK OF PAST MONTH (Additional questions about the effect of alcohol on social and occupational functioning may be necessary.) E22

1. Mild: Few, if any, symptoms in excess of those required to make the diagnosis, and the symptoms result in no more than mild impairment in occupational functioning or in usual social activities or relationships with others (or criteria met for Dependence in the past and some current problems).

2. Moderate: Symptoms or functional impairment between "mild" and "severe".

3. Severe: Many symptoms in excess of those required to make the diagnosis, and the symptoms markedly interfere with occupational functioning or with usual social activities or relationships with others.

GO TO NON-ALCOHOL USE DISORDERS, E. 10

?=inadequate information 1=absent or false 2=subthreshold 3=threshold or true

APPENDIX 2

DSM-IV-TR Alcohol Dependence criteria- Diagnostic Code 303.90

A maladaptive pattern of alcohol use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

(1) tolerance, as defined by either of the following:

(a) a need for markedly increased amounts of alcohol to achieve Intoxication or desired effect

(b) markedly diminished effect with continued use of the same amount of alcohol

(2) Withdrawal, as manifested by either of the following:

(a) the characteristic withdrawal syndrome for alcohol

(b) alcohol (or a closely related drug such as valium) is used to relieve or avoid withdrawal symptoms.

(3) alcohol is often used in larger amounts or over a longer period than was intended

(4) there is a persistent desire or unsuccessful efforts to cut down or control alcohol use

(5) a great deal of time is spent in activities necessary to obtain alcohol, use alcohol, or recover from its effects

(6) important social, occupational, or recreational activities are given up or reduced because of alcohol use

(7) alcohol use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol (e.g. continued drinking despite recognition that an ulcer was made worse by alcohol consumption)

APPENDIX 3

SEVERITY OF ALCOHOL DEPENDENCE QUESTIONAIRE (SADQ-C)[1]

Please recall a typical period of heavy drinking in the last 6 months.
When was this? Month:……. Year……..
Please answer all the following questions about your drinking by circling your most appropriate response.

During that period of heavy drinking

1. The day after drinking alcohol, I woke up feeling sweaty.
ALMOST NEVER SOMETIMES OFTEN NEARLY ALWAYS

2. The day after drinking alcohol, my hands shook first thing in the morning.
ALMOST NEVER SOMETIMES OFTEN NEARLY ALWAYS

3. The day after drinking alcohol, my whole body shook violently first thing in the morning if I didn't have a drink.
ALMOST NEVER SOMETIMES OFTEN NEARLY ALWAYS

4. The day after drinking alcohol, I woke up absolutely drenched in sweat.
ALMOST NEVER SOMETIMES OFTEN NEARLY ALWAYS

5. The day after drinking alcohol, I dread waking up in the morning.
ALMOST NEVER SOMETIMES OFTEN NEARLY ALWAYS

6. The day after drinking alcohol, I was frightened of meeting people first thing in the morning.
ALMOST NEVER SOMETIMES OFTEN NEARLY ALWAYS

7. The day after drinking alcohol, I felt at the edge of despair when I awoke.
ALMOST NEVER SOMETIMES OFTEN NEARLY ALWAYS

8. The day after drinking alcohol, I felt very frightened when I awoke.
ALMOST NEVER SOMETIMES OFTEN NEARLY ALWAYS

9. The day after drinking alcohol, I liked to have an alcoholic drink in the morning.
ALMOST NEVER SOMETIMES OFTEN NEARLY ALWAYS

10. The day after drinking alcohol, I always gulped my first few alcoholic drinks down as quickly as possible.
ALMOST NEVER SOMETIMES OFTEN NEARLY ALWAYS

11. The day after drinking alcohol, I drank more alcohol to get rid of the shakes.
ALMOST NEVER SOMETIMES OFTEN NEARLY ALWAYS

12. The day after drinking alcohol, I had a very strong craving for a drink when I awoke.
ALMOST NEVER SOMETIMES OFTEN ALMOST ALWAYS

13. I drank more than a quarter of a bottle of spirits in a day (OR 1 bottle of wine OR 7 beers).
ALMOST NEVER SOMETIMES OFTEN ALMOST ALWAYS

14. I drank more than half a bottle of spirits per day (OR 2 bottles of wine OR 15 beers).
ALMOST NEVER SOMETIMES OFTEN ALMOST ALWAYS

15. I drank more than one bottle of spirits per day (OR 4 bottles of wine OR 30 beers).
ALMOST NEVER SOMETIMES OFTEN ALMOST ALWAYS

16. I drank more than two bottles of spirits per day (OR 8 bottles of wine OR 60 beers)
ALMOST NEVER SOMETIMES OFTEN ALMOST ALWAYS

Imagine the following situation:
1. You have been **completely off drink for a few weeks**
2. You then drink **very heavily** for **two days**

How would you feel the **morning after** those two days of drinking?

17. I would start to sweat.
NOT AT ALL SLIGHTLY MODERATELY QUITE A LOT

18. My hands would shake.
NOT AT ALL SLIGHTLY MODERATELY QUITE A LOT

19. My body would shake.
NOT AT ALL SLIGHTLY MODERATELY QUITE A LOT

20. I would be craving for a drink.
NOT AT ALL SLIGHTLY MODERATELY QUITE A LOT

SCORE

CHECKED BY:

ALCOHOL DETOX PRESCRIBED: YES/NO

APPENDIX 4

SEVERITY OF ALCOHOL DEPENDENCE QUESTIONNAIRE (Tamil translated version)

பெயர் : வயது : தேதி :

கடந்த 6 மாதங்களில் மிக அதிகமாக அது அருந்தியதை நினைவு கூறவும்.

எப்பொழுது? மாதம் : வருடம் :

உங்களின் குடிப்பழக்கம் குறித்த பின்வரும் கேள்விகளுக்கு உங்கள் பதில்களை வட்டமிட்டு காட்டவும்.

மிக அதிகமாக மது அருந்தும் காலங்களில் :

1 மது அருந்திய அடுத்த நாள் நான் எழுந்திருக்கும் போது அதிகமாக வியர்வையை உணர்கிறேன்.

எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்

2 மது அருந்திய அடுத்த நாள் காலை எழுந்தவுடன் மன் கைகள் நடுங்குவதை உணர்கிறேன்.

எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்

3 மது அருந்திய அடுத்த நாள் மது அருந்தவில்லை எனில் எனது உடல் மிகத் தீவிரமாக நடுங்குவதை உணர்கிறேன்.

எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்

4 மது அருந்திய அடுத்த நாள் நான் எழும் போது முழுவதும் வியர்வையில் நனைந்திருக்கிறேன்.

எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்

5 மது அருந்திய அடுத்த நாள் காலையில் பெரும் பயத்துடன் எழுந்திருக்கிறேன்

எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்

6 மது அருந்திய அடுத்த நாள் காலையில் பிறரை சந்திக்கும் போது பயப்படுகிறேன்

எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்

7	மது அருந்திய அடுத்த நாள் காலையில் எழும் போது நம்பிக்கை இல்லாதது போல் உணர்கிறேன்			
	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
8	மது அருந்திய அடுத்த நாள் காலையில் எழுந்த பின் பயத்தை உணர்கிறேன்			
	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
9	மது அருந்திய அடுத்த நாள் மீண்டும் காலையில் மது அருந்த விரும்புகிறேன்			
	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
10	மது அருந்திய அடுத்த நாள் மீண்டும் மது அருந்தும் போது முதலில் சிறிது மதுவை மிக வேகமாக விழுங்குகிறேன்			
	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
11	மது அருந்திய அடுத்த நாள் நடுக்கத்தைக் குறைப்பதற்காக அதிக அளவு அருந்துகிறேன்			
	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
12	மது அருந்திய அடுத்த நாள் காலையில் எழும் போது மதுவின் மீது ஆர்வம் அதிகமாகிறது			
	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
13	நான் ஒரு நாளைக்கு ஒரு குவார்ட்டர் சாராயம் (1 ஔயின் அல்லது 7 பீர்) அதற்கு மேல் குடிக்கிறேன்			
	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
14	நான் ஒரு நாளைக்கு அரை பாட்டில் சாராயம் (2 பாட்டில் ஔயின் அல்லது 15 பீர்) அதற்கு மேல் குடிக்கிறேன்			
	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்

15 நான் ஒரு நாளைக்கு ஒரு பாட்டில் சாராயம் (4 பாட்டில் ஒயின் அல.லது 30 பீர்) அதற்கு மேல் குடிக்கிறேன்

எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்

16 நான் ஒரு நாளைக்கு 2 பாட்டில் சாராயம் (8 பாட்டில் ஒயின் அல.லது 60 பீர்) அதற்கு மேல் குடிக்கிறேன்

எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்

பின் வரும் நிகழ்வுகளை கற்பனை செய்யவும்

1 நீங்கள் சில வாரங்கள் மது அருந்துவதை முற்றிலும் நிறுத்தி விட்டீர்கள்
2 அதற்கு அடுத்த 2 நாட்கள் மிக அதிகமாக மது அருந்துகிறீர்கள்
3 இரண்டு நாட்கள் கழந்தபின் காலையில் எப்படி உணர்வீர்கள்?

17 எனக்கு வியர்க்க ஆரம்பிக்கும்
ஒரு போதும் இல்லை கொஞ்சம் மிதமாக மிக அதிகமாக

18 எனது கைகள் நடுங்கும்
ஒரு போதும் இல்லை கொஞ்சம் மிதமாக மிக அதிகமாக

19 எனது உடல் நடுங்கும்
ஒரு போதும் இல்லை கொஞ்சம் மிதமாக மிக அதிகமாக

20 எனக்கு மதுவின் மீது தீவரம் அதிகரிக்கும்
ஒரு போதும் இல்லை கொஞ்சம் மிதமாக மிக அதிகமாக

APPENDIX 5

Clinical **Instituite withdrawal assessment for Alcohol scale - revised**

Addiction Research Foundation

Clinical Institute Withdrawal Assessment for Alcohol, Revised (CIWA – Ar)

Patient: _____ Pulse or heart rate, take for 1 minute: _____

Date: _____ Time: _____ Blood Pressure: _____

Nausea and Vomiting: Ask, "Do you feel sick to your stomach? Have you vomited?" Observation:

0 No nausea and no vomiting
1 Mild nausea and no vomiting
2
3
4 Intermittent nausea with dry heaves
5
6
7 Constant nausea, frequent dry heaves and vomiting.

Tactile Disturbance: Ask, "Have you any itching, pins and needles sensations, any burning, any numbness, or do you feel bugs crawling under your skin?" Observation:

0 None
1 Very mild itching, pins and needles, burning or numbness
2 Mild itching, pins and needles, burning or numbness
3 Moderate itching, pins and needles, burning or numbness
4 Moderate severe hallucinations
5 Severe hallucinations
6 Extremely severe hallucinations
7 Continuous hallucinations

Tremor: Arms extended and fingers spread apart. Observation:

0 No tremor
1 Not visible but can be felt fingertip to fingertip
2
3
4 Moderate, with patient's arm extended
5
6
7 Severe, even with arms not extended

Auditory Disturbances: Ask, "Are you more aware of sounds around you? Are they harsh? Do they frighten you? Are you hearing anything that is disturbing to you? Are you hearing things you know are not there?" Observation:

0 Not present
1 Very mild harshness or ability to frighten
2 Mild harshness or ability to frighten
3 Moderate harshness or ability to frighten
4 Moderately severe hallucinations
5 Severe hallucinations
6 Extremely severe hallucinations
7 Continuous hallucinations

Paroxysmal Sweats: Observation:

0 No sweat visible
1
2
3
4 Beads of sweat obvious on forehead
5
6
7 Drenching sweats

Visual Disturbances: Ask, "Does the light appear to be too bright? Is the color different? Does it hurt your eyes? Are you seeing anything that is disturbing to you? Are you seeing things you know are not there?" Observation:

0 Not present
1 Very mild sensitivity
2 Mild sensitivity
3 Moderate sensitivity
4 Moderately severe hallucinations
5 Severe hallucinations
6 Extremely severe hallucinations
7 Continuous hallucinations

Addiction Research Foundation

Clinical Institute Withdrawal Assessment for Alcohol, Revised (CIWA – Ar)

Patient: _____ Pulse or heart rate, take for 1 minute: _____

Date: _____ Time: _____ Blood Pressure: _____

Anxiety: Ask, "Do you feel nervous?"
Observation:

0 No anxiety, at ease
1 Mildly anxious
2
3
4 Moderately anxious, or guarded, so anxiety is inferred
5
6
7 Equivalent to acute panic states, as seen in severe delirium or acute schizophrenic reactions

Headache, Fullness in Head: Ask, "Does your head feel different? Does it feel like there is a band around your head?" Do not rate dizziness or lightheadedness. Otherwise, rate severity.

0 Not present
1 Very mild
2 Mild
3 Moderate
4 Moderately severe
5 Severe
6 Very severe
7 Extremely severe

Agitation: Observation

0 Normal activity
1 Somewhat more than normal activity
2
3
4 Moderately fidgety and restless
5
6
7 Paces back and forth during most of the interview, or constantly thrashes about

Orientation and Clouding of Sensorium: Ask, "What day is this? Where are you? Who am I?" Observation:

0 Oriented and can do serial additions
1 Cannot do serial additions or is uncertain about date
2 Disoriented for date by no more than 2 calendar days
3 Disoriented for date by more than 2 calendar days
4 Disoriented for place and/or person

Total **CIWA – Ar** Score _____
(maximum possible score = 67)

Rater's Initials _____

Patients scoring less than 10 do not usually need additional medication for withdrawal.

APPENDIX 6:

Clinical Instititute Withdrawal Assessment for Alcohol Scale (CIWA-Ar) –Tamil transalted version

CIWA – AR - TAMIL

1 வயிற்றைப் பிறட்டுவது போல் உள்ளதா? வாந்தி எடுத்துள்ளீர்களா?

0) வயிற்றைப் பிறட்டவோ வாந்தி எடுக்கவோ இலலை

1) லேசாக பிறட்டுகிறது ஆனால் வாந்தி இல்லை

2)

3)

4) அவ்வப்போது வயிற்றைப் பிறட்டி. வாந்தி எடுப்பது போல் உள்ளது

5)

6)

7) தொடர்ந்து எப்போதும் வயிற்றுப் பிறட்டல் மற்றும் வாந்தி இருக்கிறது.

2 நடுக்கம்
நோயாளியின் இரண்டு கைகளையும் தங்கள் முன் நீட்டி விரல்களை விரிவுபடுத்தி காண்பிக்க சொல்லுங்கள்
0) நடுக்கம் இல்லை
1) பார்ப்பதற்கு நடுக்கம் இல்லை ஆனால் நமது விரல் நுனி நோயாளியின் விரல் நுனி மேல் வைத்துப் பார்த்தால் நடுக்கம் உணரமுடிகிறது.
2)
3)
4) கைகளை முன் நீட்டினால் நடுக்கம் அதிகமாக இருக்கிறது
5)
6)
7) கைகளை நீட்டாமலே. நடுக்கம் மிக அதிகமாக தெரிகிறது.

3) வியர்வை

0) வியர்வை இல்லை

1) உள்ளங்கையில் மட்டும் வியர்வை உள்ளது

2)

3)

4) வியர்வை துளிகள் நெற்றியில் தெரிகிறது

5)

6)

7) வியர்வையில் குளித்தது போல் உள்ளது

4) மனப்பதற்றம் :

நோயாளியிடம், "உங்களுக்கு மனப்பதற்றம் உள்ளதா?" என்று கேளுங்கள்

0) மனபதற்றம் இல்லை
1) லேசான மனபதற்றம் இருக்கிறது
2)
3)

4) மிதமான மனப்பதற்றம் இருக்கிறது / நோயாளி மனப்பதற்றம் இல்லை என்று கூறினாலும், பார்ப்பதற்கு பதற்றமாக இருக்கிறார்.

5)

6)

7) பீதி அடைந்தது போல் உள்ளார்

5. தொட்டுணர்ச்சி தொந்தரவு

நோயாளியிடம். "உங்களுக்கு அரிப்பு. ஊசி குத்துவது போன்ற உணர்வு, எரிச்சல், மரமரப்பு அல்லது உங்கள் தோல் மீதோ அல்லது உள்ளேயோ பூச்சி ஊர்வது போல் உள்ளதா என்று கேளுங்கள்.

0) இல்லை

1) மிகவும் லேசாக

2) லேசாக

3) மிதமாக

4) ஓரளவு கடுமையான பிரமைகள்

5) கடுமையான பிரமைகள்

6) மிகவும் கடுமையான பிரமைகள்

7) பிரமைகள் தொடர்ந்து ஏற்பட்ட வண்ணம் உள்ளன.

6 செவிபுல தொந்தரவுகள்

நோயாளியிடம் தங்களை சுற்றியுள்ள ஓசைகளைப் பற்றிய விழிப்புணர்வு அதிகமாக உள்ளதா? அந்த ஓசைகள் கடுமையாக உள்ளதா?

தங்களை தொந்தரவு செய்யும் வகையில் காதில் ஒலி கேட்கிறதா? தங்களை பயமுறுத்துவது போல் உள்ளதா? நீங்கள் உண்மையில் இல்லாத ஒலிகளை கேட்கிறீர்களா?

0) இல்லை

1) மிகவும் லேசாக கடுமையான சொற்கள் ஒலிக்கிறது பயமுறுத்துவது போல் உள்ளது

2) லேசாக கடுமையான சொற்கள் ஒலிக்கிறது பயமுறுத்துவது போல் உள்ளது

3) மிதமான கடுமையான சொற்கள் ஒலிக்கிறது பயமுறுத்துவது போல் உள்ளது

4) கடுமையான ஒலி பிரமை

5) மிகவும் கடுமையான ஒலி பிரமை உள்ளது.

6) மிக மிக கடுமையான ஒலி பிரமை உள்ளது

7) எப்போதும் ஒலி கேட்ட வண்ணம் உள்ளது

7. காட்சி பிரமைகள் மற்றும் தொந்தரவுகள்

நோயாளியிடம, "ஒளி மிகவும் பிரகாசமாக தெரிகிறதா?'. அது உங்களது கண்களை காயப்படுத்துவது போல் உள்ளதா? உங்களை தொந்தரவு செய்வது போல் ஏதாவது காண்கிறீர்களா? நீங்கள் உண்மை இல்லாதவை ஏதேனும் காண்கிறீர்களா?

0) இல்லை

1) மிகவும் லேசாக உணர்கிறேன்

2) லேசாக உணர்கிறேன்

3) மிதமாக உணர்கிறேன்

4) ஓரளவு கடுமையாக உணர்கிறேன்

5) கடுமையான காட்சி பிரமைகள்

6) மிகவும் கடுமையான காட்சி பிரமைகள்

7) காட்சி பிரமைகள் தொடர்ந்து வந்த வண்ணம் உள்ளன

8. தலை வலி:

தலை கனத்து தோன்றுதல்

நோயாளியிடம், "உங்களது தலையில் ஏதேனும் வித்தியாசம் உள்ளதா?" தங்களது தலையை சுற்றி கயிறு கட்டியது போல் தோன்றுகிறதா?

(மயக்க உணர்வையோ, தலை சுற்றுவது பற்றியோ கேட்க வேண்டாம்)

0) இல்லை

1) மிகவும் லேசாக உள்ளது

2) லேசாக உள்ளது

3) மிதமாக உள்ளது

4) ஓரளவு கடுமையாக உள்ளது

5) கடுமையாக உள்ளது

6) மிகவும் கடுமையாக உள்ளது

7) மிக மிக கடுமையாக உள்ளது

9 கிளர்ச்சி :

0) இயல்பான நடவடிக்கை
1) இயல்பை விட மாறுபட்ட நடவடிக்கை
2)
3)
4) மிதமான அமைதியின்மை, அமைதியில்லாமல் அசைந்து கொண்டே இருத்தல்
5)
6)
7) நேர்கானலுக்கு ஒத்துழைக்காமல். முன்னும் பின்னுமாக நடத்தல்

10. தன்னிலை அறிதல் மற்றும் விழிப்புணர்வு மங்கலான தோற்றம்

நோயாளியிடம், "இன்று என்ன தேதி?"

"நீங்கள் எங்கு உள்ளீர்கள்?" "நான் யார்?"

0) தன்னிலை அறிந்துள்ளார் மற்றும் தொடர் சேர்த்தல் செய்ய இயலும்
1) தன்னிலை அறிந்துள்ளார் ஆனால் தொடர் சேர்த்தல் செய்ய இயலாது தேதி தெரியவில்லை

2) நாள்காட்டியில் உள்ள தேதிக்கும் நோயாளி சொன்ன தேதிக்கும் வித்தியாசம் உள்ளது ஆனால் அது இரண்டு நாட்களுக்குமேல் இல்லை.

3) நாள்காட்டியில் உள்ள தேதிக்கும் நோயாளி சொன்ன தேதிக்கும் வித்தியாசம் உள்ளது ஆனால் இரண்டு நாட்களுக்கு மேல் உள்ளது.

4) நோயாளி எங்குள்ளார் என்றோ. யாரிடம் பேசிக்கொண்டிருக்கிறார் என்றோ தெரியவில்லை.

APPENDIX 7

DATA COLLECTION PROFORMA

1. **Name:**
2. **Age:**
3. **Sex:**
4. **I.P No.**
5. **Marital Status:** Married/ Unmarried/separated/divorced
6. **Socio-Economic Status:***(*average monthly income*)*
7. **Smoking**:

   Yes/No. If Yes, then Specify No. of cigarettes /beedies per day :_____

8. **Other Substance use:**

   Yes/No. If Yes, then Specify _____

9. **Medical Illness:**

10. **SCID INTEVIEW SCHEDULE FOR ALCOHOL DEPENDENCE SYNDROME**

11.<u>SADQ :</u>

- Questionairre

- Total Score:
- Impression:

12. <u>CIWA-Ar Score:</u>

	Ciwa-Ar	Chlordiazepoxide (C)/ Lorazepam (L)	Total dose of BZD
Day 1 (Baseline)			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			

Total Dose of Chlordizapoxide / Lorazepam received : _____mg

13.

	Withdrawal Complications
Day 1	
Day 2	
Day 3	
Day 4	
Day 5	
Day 6	
Day 7	

14.CSQ Score

	CSQ Score
Day 2	
Day 3	
Day 4	
Day 5	
Day 6	
Day 7	

APPENDIX 8

CIWA- Ar scoring sheet

	6 am	7 am	8 am	9 Am	10 am	11 Am	12 noon	1 pm	2 pm	3 pm	4 pm	5 pm
Nausea and vomitting												
Tremor												
Paroxysmal sweats												
Anxiety												
Agitation												
Tactile disturbances												
Auditory disturbances												
Visual disturbances												
Headache, fullness in head												
Orientation and clouding of sensorium												
Total score												
Benzodiazepine * dose(if total score >10)												

* Write as ‘L 1mg’ for lorazepam and ‘C20mg’ for Chlordiazepoxide

	6 pm	7 pm	8 pm	9 pm	10 pm	11 Pm	12 Mid night	1 am	2 am	3 am	4 am	5 am
Nausea and vomitting												
Tremor												
Paroxysmal sweats												
Anxiety												
Agitation												
Tactile disturbances												
Auditory disturbances												
Visual disturbances												
Headache, fullness in head												
Orientation and clouding of sensorium												
Total score												
Benzodiazepine * dose(if total score >10)												

APPENDIX 9

Informed Consent – English Version

PSG Institute of Medical Science and Research, Coimbatore
Institutional Human Ethics Committee
INFORMED CONSENT FORMAT FOR STUDENT RESEARCH PROJECTS

I

Post Graduate (M.D Psychiatry), Year 2010, Regular Batch student of the PSG Institute of Medical Sciences & Research (PSG IMS&R), am carrying out a study on the topic: Symptom – Triggered Therapy for Alcohol Withdrawal by using Revised Clinical Institute Withdrawal Assessment of Alcohol Scale (CIWA-Ar) by nursing staff – a Randomised Control Study as part of my student research project being carried out under the aegis of the Department of Psychiatry

Our research guide is Prof. Raghuthaman
; Designation: Head of Department

The justification for this study is:

To compare between the symptom triggered regimen and fixed schedule regimens for treatment of alcohol related withdrawal symptoms. .

The aims of this study are:

Primary Aim: To calculate mean dose of Librium administered and duration of treatment in both fixed schedule group and symptom triggered group

Secondary Aims: Occurrence of any withdrawal complications like delirium tremens and rum fits.

Sample size: 50. **Respondents** are All the consecutive patients, between the ages of 16 and 65 years, admitted to our psychiatry ward with the

diagnosis of alcohol dependence syndrome. **Location**: PSGIMSR, Coimbatore.

We request you to kindly cooperate with us in this study. We propose collect background information and other relevant details related to this study. We will be carrying out **Initial interview**: 30 minutes.

Medication given would be chlordiazepoxide or lorazepam during the detoxification period either according to symptom triggered or the fixed schedule regimen.

Final interview : 30 mts.

Benefits from this study, if any: Lesser duration of stay in hospital and prevention of major withdrawal symptoms like delirium tremens.

How the **results** will be used: For adopting better regimens for treatment of alcohol related withdrawal symptoms.

If you are uncomfortable in answering any of our questions during the course of the interview / biological sample collection, **you have the right to withdraw from the interview / study at anytime.** You have the freedom to withdraw from the study at any point of time. Kindly be assured that your refusal to participate or withdrawal at any stage, if you so decide, will not result in any form of compromise or discrimination in the services offered. You will continue to have access to the regular services offered to a patient. You will **NOT** be paid any remuneration for the time you spend with us for this interview / study. The information provided by you will be kept in strict confidence. Under no circumstances shall we reveal the identity of the respondent or their families to anyone. The information that we collect shall be used for approved research purposes only.

Consent: The above information regarding the study, has been read by me/ read to me, and has been explained to me by the student investigators from the PSG IMS&R. Having understood the same, I hereby give my consent to them to interview me. I affixing my signature / left thumb impression to indicate my consent and willingness to cooperate in this study.

Respondent ID: _____.
Signature / Left thumb impression of the Respondent.

Signature of the Interviewer with date

APPENDIX 10

Informed Consent form- Tamil Version

ஒப்புதல் படிவம்

பெயர் : தேதி :

முகவரி :

..... ஆகிய நான் .....

..... என்ற ஆராய்ச்சிக்கு முழுமனதுடன் சம்மதிக்கிறேன்.

நான் இந்த ஆராய்ச்சியின் நோக்கம் மற்றும் அதன் பயன்பாட்டினைப் பற்றி தெளிவாகவும், விளக்கமாகவும் தெரியப்படுத்த ப்பட்டுள்ளேன்.

இந்த ஆய்வில் பங்கேற்க ஒப்புக்கொள்ளுவதால் எந்த விதமான பலனும் எனக்குக் கிடைக்காது. என்றும், எந்த நேரத்தில் வேண்டுமானாலும் ஆய்விலிருந்து விலகிக்கொள்ளும் உரிமை எனக்கு உண்டு என்றும் தெரியப்படுத்தப்பட்டுள்ளேன்.

இந்த ஆராய்ச்சியின் மருத்துவ ரீதியான குறிப்புகளை வரும் காலத்திலும் உபயோகப்படுத்திக்கொள்ள முழு மனதுடன் சம்மதிக்கிறேன்.

ஆய்வுக்குட்படுபவரின் கையொப்பம் :

தேதி :

ஆய்வாளரின் கையொப்பம் :

தேதி :